SUPREME COURT, U. S.

Supreme Court, U. S.

DEC 16 1974

MICHAEL RODAK, JR., CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-501

WYETH LABORATORIES, a Division of American Home Products Corporation, a Delaware corporation,
Petitioner,

v.

EPIFANIO REYES, individually and as next friend of Anita Reyes, a minor,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

PETITIONER'S REPLY TO RESPONDENT'S BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

(Signatures on Page 2 of Cover)

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Respondent's Brief in Opposition to Petition for a Writ of Certiorari contains numerous erroneous or misleading statements of fact, and fails to respond adequately to the legal arguments advanced by Petitioner.

I.

On page 2 of his Brief, Respondent asserts that neither of the questions presented in the Petition for a Writ of Certiorari was raised in the lower courts. This is simply not true. Petitioner argued in the trial court and in the Court of Appeals that Sabin oral polio vaccine is a prescription drug, licensed by the Federal Government for sale only as a prescription drug under the appropriate Federal statutes. *See* 42 U.S.C. § 262(a); 21 U.S.C. § 353(b); 42 C.F.R. §§ 72.200-.240 and 73.1020-.1028 (all of which were cited and relied upon in Petitioner's appellate brief). Petitioner therefore had no duty under local tort law to warn the ultimate consumer of its vaccine. Wyeth has consistently maintained that Federal law controlled regarding the discharge of its duty as a manufacturer of prescription drugs and that, in the absence of a holding that it provided an inadequate warning to the appropriate health authorities responsible for dispensing the drug, it could not be held liable.

Respondent has failed to refute Petitioner's argument that the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040 (1938), as amended, 21 U.S.C. § 301, *et seq.* (1970), and the Public Health Service Act, 58 Stat. 702 (1944), as amended, 42 U.S.C. § 262, *et seq.* (1970), have preempted the field of law applicable to the labeling of prescription biological drug products and that it was therefore error for the lower courts to dispose of this case solely on the basis of local tort law.

Petitioner has established that the labeling of prescription drug products shipped in interstate commerce is subject entirely to Federal law and regulation and

that the States are without power to impose contrary restraints in this area. It is undisputed that Sabin oral polio vaccine is a prescription drug and that Wyeth fully complied with the provisions of Federal law regarding the labeling of this product. Respondent's contention that the package insert which accompanied the vaccine was inadequate is unfounded, and was not adopted by any of the lower courts. Moreover, this contention turns entirely on the very Federal law which Respondent argues is not controlling here.

Once the manufacturer of a prescription drug has complied fully with the provisions of Federal law regarding the labeling of its product and has furnished this warning to the health professionals responsible for administering the drug, the manufacturer has completed his obligation to the public. To require the manufacturer of a prescription drug to provide written material to the ultimate consumer other than the labeling required by Federal law subjects the manufacturer to obligations inconsistent with the requirements of Federal law and interjects State tort law into an area which Congress has clearly pre-empted.

II.

The second question raised in the Petition for Certiorari, that the Court of Appeals erred in its application of Texas law, was thoroughly briefed in the lower courts. A substantial portion of Petitioner's appellate brief was devoted to the proposition that Wyeth had no duty under Texas law to warn the ultimate consumer of the dangers inherent in its drug. Moreover, *Gravis* v. *Parke-Davis & Co.*, 502 S.W.2d 863 (Tex. Civ.App.—Corpus Christi, 1973), relied upon by Wyeth

in its Petition for Certiorari, was not decided until after its appellate brief had been submitted to the Court of Appeals. That the Court of Appeals considered *Gravis* is obvious. It was cited as Texas authority for the elements which must be established to recover under § 402(a) of the Restatement (Second) of Torts. 498 F.2d at 1272; Appendix A to the Petition for Certiorari at p. 8(a). Respondent's assertion that the second question raised in the Petition for Certiorari was not presented to the courts below is groundless.

Although the Court of Appeals cited and applied a portion of the *Gravis* holding, the court failed to discuss or even mention the following statement from *Gravis*, 502 S.W.2d at 870:

> "We hold that it is unreasonable to demand that the manufacturer of drugs specifically warn each and every patient that receives drugs prescribed by the physician *or other authorized persons.* The entire system of drug distribution in America is set up so as to place the responsibility for distribution and use upon professional people. The laws and regulations prevent prescription-type drugs from being purchased by individuals without the advice, guidance and consent of licensed physicians and pharmacists. These professionals are in the best position to evaluate the warnings put out by the drug industry." (Emphasis added.)

The Court of Appeals' holding in *Reyes* v. *Wyeth* cannot be reconciled with this Texas court decision, and Respondent makes no attempt to do so in its Brief. In view of the practical consequences of the Court of Appeals' decision, fully discussed in the Petition for Certiorari filed herein, this conflict with Texas law is a sufficient basis on which to grant the Petition.

III.

There are several inaccurate and misleading references in Respondent's Brief which require clarification. The last paragraph of page 3 of Respondent's Brief refers to the Report of Surgeon General's Committee on Oral Poliomyelitis Vaccines, which was published in July 1964. Respondent's use of that report distorts the findings of the Committee. Respondent does not mention the Committee's conclusion that it was not possible to prove that any individual case was caused by the vaccine and that no laboratory tests available could provide a definite answer. The Committee's conclusion was simply that "considering the epidemiological evidence developed with respect to the total group of 'compatible' cases, the Committee believes that at least some of these cases were caused by the vaccine."

The same report outlined the "risk factor" associated with the oral vaccine and concluded as follows:

> "For Type III, only 1 case in 2.5 million doses administered; for Type I, only 1 in 6 million; and for Type II, only 1 in 50 million."

On page 7 of Respondent's Brief, reference is made to the testimony of Dr. John P. Fox, Associate Dean, School of Public Health, and Professor of Epidemiology, University of Washington. Respondent fails to point out that when asked to express an opinion regarding the origin of Respondent's illness, Dr. Fox attributed the illness to a virus of "wild origin" and further testified that:

> "It was not Type I vaccine virus, it was virus which had infected her probably prior to the administration of the vaccine, and which was circulat-

> ing rather abundantly in the neighborhood as is evidenced from the occurrences of other cases at about this time." Court of Appeals Appendix, p. 1166

Respondent's intimation that Sabin oral polio vaccine is more dangerous than other vaccines (Respondent's Brief, p. 11) is conclusively refuted by the testimony of Dr. Fox. Speaking of the relative safety of the Sabin vaccine, Dr. Fox stated that:

> "Amongst those that have been licensed and used, almost the safest that I can think of are the live polio vaccines. The frequency of disease attributable to the use of these vaccines is of such a low order of magnitude that offhand I cannot think of anything comparable to it. . . ." Court of Appeals Appendix, pp. 1169-1170

Respondent's reference to the testimony of Dr. Neal Nathanson, Professor of Epidemiology at Johns Hopkins University, and Editor of the American Journal of Epidemiology, is misleading and largely meaningless. Dr. Nathanson's reference to a risk of vaccine induced polio of one in 5000 was based on an assumption of the very fact at issue, i.e., that Respondent's disease was vaccine induced. When asked to assess the odds of vaccine induced disease in Respondent's case, Dr. Nathanson stated: "I would calculate that I would be 99.9 percent certain that this case was a naturally acquired case of polio." He added that he "felt that there was no clear reason to consider any of these cases (those in Hidalgo County) as vaccine related." Court of Appeals Appendix at 1383, 1381.

CONCLUSION

Respondent's Brief in Opposition to the Petition for a Writ of Certiorari fails to diminish the weight of the reasons advanced for granting the Writ. Of particular importance is the disruptive effect which the decision below will have on the public health system of this country. The importance of this issue is illustrated by the concern of such groups as the American Medical Association, the American Academy of Pediatrics, and The Conference of State and Territorial Epidemiologists, all of whom have moved for leave to file briefs *amici curiae* in support of the Petition. In view of the gravity of this issue, we urge this Court to grant a Writ of Certiorari to review the opinion of the United States Court of Appeals for the Fifth Circuit.

Respectfully submitted,

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